

## **ATTACHMENT A**

### **Remarks**

Applicant wishes to thank the Examiners, Mr. Willse and Ms. Miller for the courteous interview granted to Applicant's attorney, Mr. Petry, on November 16, 2004. In accordance with the provisions of Rule 133(b), the reasons brought out at the interview as warranting favorable action are set forth below.

Claims 55-86 remain in this application.

The rejections under 35 U.S.C. § 112, noted on pages 3 and 4 of the Final Rejection have been carefully noted and the claims have been amended as required to satisfy each and every one of those rejections. It was noted at the interview that the phrase "the shorter sides" is permissible as is. Regarding the objection on page 4 regarding "the height of the remainder of their respective parts", it is believed that these claims have been carefully amended to clarify that the height is being compared to the remainder of the individual part, not to the entire implant.

In the Final Rejection, the independent claims 55 and 73 were rejected under § 102 as being anticipated by Zdeblick and Bullivant and as being obvious in view of Marnay. For reasons set forth at the interview, reflecting many of the points presented in the previous Amendment, including the Dr. Marnay Declaration, and as set forth below and considering the current clarifying amendments to the claims, it is believed that independent claims 55 and 73 as well as their dependent claims are clearly patentable over the prior art.

In the Final Rejection, the Examiner acknowledged the significant points made in the Marnay Declaration but then set forth the rejections based primarily on the position that the use of a single anchor on intervertebral implants was well known in the art.

At the interview, Applicant's attorney discussed the primary references relied upon in the Office Action and as a result thereof, it was agreed that such arguments, together with the proposed amendments to claim 55 and a thorough analysis of the Zdeblick reference, and in particular the nature of the implant shown in Figure 34 thereof as not being used alone, would render claim 55 allowable over the references of record (although a further search would be conducted before the application could be officially allowed).

Applicant's attorney noted that independent claim 73 would also be amended to include, in substance, the same limitations as being made to claim 55. It would be noted, however, that since claim 73 was already limited, relative to claim 55, to generally rectangular upper and lower parts, the precise amendments to claim 73 in order to render it similar to the limitations added to claim 55 would not quite be the same.

As noted at the interview, the present invention provides an intervertebral implant having a single anchor above the upper surface of the upper part and a similar coplanar single anchor below the lower part, wherein the anchors are of a sufficient height to be received in a groove cut into the adjacent vertebrae. Anchors of this type which are of a height to be received into grooves cut into the adjacent vertebrae are more clearly shown in Dr. Marnay's prior U.S. Patent No. 5,314,477, which is referred to in the present application.

An anchor received in a groove cut into the adjacent vertebrae provides a very significant anchor and is different from smaller barbs, interruptions, scales and shorter ribs which are not of a height sufficient to enter a groove cut into the adjacent vertebrae, but instead are intended to engage directly that surface of the adjacent vertebrae which faces into the intervertebral space. Indeed, the present application illustrates such other types of elements such as the smaller protrusions 7 which are clearly not contemplated by the present inventor to constitute anchors and do not in fact function in any manner like the anchors 6 and 14.

Dr. Marnay's Declaration set forth at great length the advantages and unobviousness of the single anchor as in the present invention as compared to the pair of anchors as shown in his prior Patent No. 5,314,477. The present application, the amendments and Declarations filed herein and the reference to Dr. Marnay's previous patent should make it crystal clear that the present invention is directed to anchors of the type described above and that they are in no way equivalent to ribs, barbs, interruptions, scales and the like which do not in any way act like an anchor of the type described herein, in Dr. Marnay's prior patent or in Dr. Marnay's Declaration, but which in fact merely engage directly that surface of the adjacent vertebrae which faces the intervertebral space.

The primary references relied upon by the Examiner to show the presence in the prior art of single anchors are the Zdeblick U.S. Patent No. 6,402,785 and the Bullivant U.S. Patent No. 5,507,816. It was agreed that if Applicant could clearly distinguish over these references, there would be no need to discuss the other references referred to in

the Final Rejection including the Hirayama et al U.S. Patent No. 4,946,378 and the Boyd et al U.S. Patent No. 5,425,773.

Referring first to Bullivant, it was noted at the interview that the two ribs 22 and 26 are not anchors as called for in the present claims. Moreover, the elements 22 and 26 which have been referred to in the Office Action are not parallel to each other and they are not in the direction from the lead end to the trailing end (as in claim 55) and they are not centrally located between the shorter sides of the generally rectangular parts (as in claim 73). In any event, it was agreed at the interview that the amendments to the independent claims that the two single anchors lie in essentially the same vertical plane would clearly distinguish over the Bullivant patent.

For the following reasons, it is also respectfully submitted that claims 55 and 73, as presented herein, are clearly patentable over the Zdeblick reference, taken alone or in combination with any other reference.

At the interview, attention was paid primarily to Figure 34 of Zdeblick which shows an implant having an upper rib 248 and a lower rib 250. This patent has now been thoroughly analyzed to more positively ascertain the structure and functioning of the embodiment shown in Figure 34. Having completed this study, and for reasons set forth below, it is believed that the present invention, as set forth in the claims presented herein, is patentable over this reference.

First, as noted at the interview, the other implants of the Zdeblick reference which were noted in the Office Action, implant 10 of Figure 1 and implant 110 of Figure 15 lack many of the elements recited in independent claims 55 and 73. First, it is Applicant's contention that the raised elements shown therein are not anchors, as described above,

but are ribs more in the nature of barbs, interruptions or scales which are intended to engage the surface of a vertebrae facing the intervertebral space and are not of the type and are not of a sufficient height to enter into a groove cut into the vertebrae. Next, even if the ribs of implant 10 were anchors, which they are not, they are not single anchors, but in fact there are three above and three below. Further, the Zdeblick specification clearly states at column 5, lines 28-34 that these straight ribs are equivalent to and could be replaced by other retention mechanisms such as barbs, interruptions, scales, etc. In a word, these function differently from the anchors of the present invention and are not the equivalent of such anchors.

In addition, referring to Figure 15, the implant 110 includes no raised structure at all along the center line 111 which would correspond to the location of Applicant's anchors in either claim 55 or claim 73.

The Zdeblick reference has also been carefully reviewed in order to ascertain the structure and function of implant 240 of Figure 34.

First, the upper and lower elements 248 and 250 are clearly not anchors of the type which form the single anchors of the present invention. Rather, they are simply ribs and there is nothing in this specification to indicate that they are anything other than the ribs which are equivalent to barbs, interruptions or scales as noted at column 5 of the specification, as discussed above which engage the surface of the vertebrae facing the intervertebral space. There is no disclosure whatsoever that they are of a sufficient height to be received in grooves cut into the adjacent vertebrae. Moreover, the very shallow height of the ribs 248 and 250, relative to the anchors as shown in the present application and in the previous Marnay patent strongly indicate that these are in fact

ribs, equivalent to barbs, interruptions or scales, and not anchors of the type of the present invention.

Additionally, a thorough reading of the specification makes it clear that the element 240 would never be used alone so that in essence, the implant for any disc space which included element 240 would necessarily include two of them such that the actual implant comprising the two elements 240 would have two ribs above and two ribs below, not single ribs or anchors and nothing would be located on the mid-line of the implant structure formed by two such elements 240.

With respect to the use of two of the implants 240, and never a single one thereof, it will be noted that the Zdeblick specification shows numerous single cylindrical elements such as in Figures 1-3 and 28-37. However, there is not one scintilla of a suggestion that these cylinders can ever be used alone. But quite to the contrary, the specification states very thoroughly and consistently that such cylindrical elements would always be used in pairs. First, note Figure 46 which is the first figure showing a cylindrical element in use and of course there are two of them. More importantly, Figures 49-51 show that in all possible orientations, an anterior approach, an anterolateral approach and a lateral approach, there are always two of these elements. In summary, the specification does not contain a scintilla of a suggestion that element 240 of Figure 34 would ever be used alone, whereas in fact the specification and drawings specifically, thoroughly and consistently describe this element as being used in pairs.

Whether used alone or in pairs, element 240 does not contain anchors of the type to which the present invention is directed. Whatever elements are present above

and below the implant 240, when placed in a patient, there are none of them along the center line as called for in the claims.

The features of the present invention which distinguish same from the references, including Zdeblick are set forth in either original or amended wording to claims 55 and 73. At the interview, it was suggested that the preamble recite that the present intervertebral implant is a total disc replacement. However, that would be erroneous and too limiting because the term "total disc replacement" would exclude an application of the present invention to situations where it could be used (by itself with no other elements) but wherein the entire disc was not replaced, for example wherein a portion of the annulus of the disc would be retained. Nonetheless, for all of the reasons set forth above, it is respectfully submitted that claims 55 and 73 distinguish patentably over Zdeblick and all of the other references.

In view of the above, it is respectfully submitted that this application is now in condition for allowance, which action is promptly and respectfully solicited.

**END REMARKS**